

ENZYMATIC THERADY - N L , AB RASED

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9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 - F: 503.582.0467

ENZYMATIC THERAPY' PHYTOPHARMICA'

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 * F: 888.570.6460 (Enzymatic) P: 920.469.9099 > F: 920.469.4418 (Phyto)

May 24, 2004

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
PRODUCT NAME Whole Heart Multivitamin™	Clinical research has also shown that maintaining healthy cholesterol and homocysteine levels, as well as intake of antioxidants, promotes cardiovascular health.*	Vitamin A (75% as beta carotene and as retinyl acetate), Vitamin C (ascorbic acid), Vitamin D (as cholecalciferol), Vitamin E (as d-alpha tocophery! acid sucinate), Thiamin (as thiamin HCI) (vitamin B1), Riboflavin (vitamin B2), Niacin (as niacinamide and niacin), Vitamin B6 (as pyridoxine HCI), Folic Acid, Vitamin B12 (as cyancobalamin), Biotin, Pantothenic Acid (as calcium D-pantothenate), Calcium (as calcium carbonate and calcium citrate), lodine (as potassium iodide), Magnesium (as magnesium aspartate and magnesium oxide), Zinc (as zinc gluconate), Selenium (as L-selenomethionine), Copper (as copper gluconate), Manganese (as manganese citrate), Chromium (as chromium picolinate), Molybdenum (as sodium molybdate), Sodium, Choline Bitartrate, Alpha Lipoic Acid, Lycopene, Lutein (from Calendula officinalis), Vanadium(as vanadyl sulfate), Zeaxanthin (from Calendula officinalis)

LET 14283 975 0162

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

Ву:

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/24/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely.



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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Whole Heart Multivitamin™	In clinical studies, use of multivitamins, containing B vitamins and folate, has been shown to also significantly reduce levels of homocysteine.*	Vitamin A (75% as beta carotene and as retinyl acetate), Vitamin C (ascorbic acid), Vitamin D (as cholecalciferol), Vitamin E (as d-alpha tocopheryl acid sucinate), Thiamin (as thiamin HCI) (vitamin B1), Riboflavin (vitamin B2), Niacin (as niacinamide and niacin), Vitamin B6 (as pyridoxine HCI), Folic Acid, Vitamin B12 (as cyancobalamin), Biotin, Pantothenic Acid (as calcium D-pantothenate), Calcium (as calcium carbonate and calcium citrate), Iodine (as potassium iodide), Magnesium (as magnesium aspartate and magnesium oxide), Zinc (as zinc gluconate), Selenium (as L-selenomethionine), Copper (as copper gluconate), Manganese (as manganese citrate), Chromium (as chromium picolinate), Molybdenum (as sodium molybdate), Sodium, Choline Bitartrate, Alpha Lipoic Acid, Lycopene, Lutein (from Calendula officinalis), Vanadium(as vanadyl sulfate), Zeaxanthin (from Calendula officinalis)

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PRODUCT NAME	<u>STATEMENTS</u>	NGREDIENT(S) TO WHICH THE CLAIM REFERS
Whole Heart Multivitamin™	Lower homocysteine levels have been shown to support healthy heart function.*	Vitamin A (75% as beta carotene and as retinyl acetate), Vitamin C (ascorbic acid), Vitamin D (as cholecalciferol), Vitamin E (as d-alpha tocopheryl acid sucinate), Thiamin (as thiamin HCI) (vitamin B1), Riboflavin (vitamin B2), Niacin (as niacinamide and niacin), Vitamin B6 (as pyridoxine HCI), Folic Acid, Vitamin B12 (as cyancobalamin), Biotin, Pantothenic Acid (as calcium D-pantothenate), Calcium (as calcium carbonate and calcium citrate), lodine (as potassium iodide), Magnesium (as magnesium aspartate and magnesium oxide), Zinc (as zinc gluconate), Selenium (as L-selenomethionine), Copper (as copper gluconate), Manganese (as manganese citrate), Chromium (as chromium picolinate), Molybdenum (as sodium molybdate), Sodium, Choline Bitartrate, Alpha Lipoic Acid, Lycopene, Lutein (from Calendula officinalis), Vanadium(as vanadyl sulfate), Zeaxanthin (from Calendula officinalis)

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Whole Heart Multivitamin™	Whole Health Multivitamin™ is a full spectrum multivitamin featuring key nutrients for targeted heart health.*	Vitamin A (75% as beta carotene and as retinyl acetate), Vitamin C (ascorbic acid), Vitamin D (as cholecalciferol), Vitamin E (as d-alpha tocopheryl acid sucinate), Thiamin (as thiamin HCI) (vitamin B1), Riboflavin (vitamin B2), Niacin (as niacinamide and niacin), Vitamin B6 (as pyridoxine HCI), Folic Acid, Vitamin B12 (as cyancobalamin), Biotin, Pantothenic Acid (as calcium D-pantothenate), Calcium (as calcium carbonate and calcium citrate), Iodine (as potassium iodide), Magnesium (as magnesium aspartate and magnesium oxide), Zinc (as zinc gluconate), Selenium (as L-selenomethionine), Copper (as copper gluconate), Manganese (as manganese citrate), Chromium (as chromium picolinate), Molybdenum (as sodium molybdate), Sodium, Choline Bitartrate, Alpha Lipoic Acid, Lycopene, Lutein (from Calendula officinalis), Vanadium(as vanadyl sulfate), Zeaxanthin (from Calendula officinalis)

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Whole Heart Multivitamin™	Elevated homocysteine levels and an inadequate intake of antioxidants are not supportive of optimal cardiovascular health.*	Vitamin A (75% as beta carotene and as retinyl acetate), Vitamin C (ascorbic acid), Vitamin D (as cholecalciferol), Vitamin E (as d-alpha tocopheryl acid sucinate), Thiamin (as thiamin HCI) (vitamin B1), Riboflavin (vitamin B2), Niacin (as niacinamide and niacin), Vitamin B6 (as pyridoxine HCI), Folic Acid, Vitamin B12 (as cyancobalamin), Biotin, Pantothenic Acid (as calcium D-pantothenate), Calcium (as calcium carbonate and calcium citrate), Iodine (as potassium iodide), Magnesium (as magnesium aspartate and magnesium oxide), Zinc (as zinc gluconate), Selenium (as L-selenomethionine), Copper (as copper gluconate), Manganese (as manganese citrate), Chromium (as chromium picolinate), Molybdenum (as sodium molybdate), Sodium, Choline Bitartrate, Alpha Lipoic Acid, Lycopene, Lutein (from Calendula officinalis), Vanadium(as vanadyl sulfate), Zeaxanthin (from Calendula officinalis)

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Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/26/04

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Whole Heart Multivitamin™	Vitamins A, C and E are antioxidants that specifically support heart health.*	Vitamin A (75% as beta carotene and as retinyl acetate), Vitamin C (ascorbic acid), Vitamin E (as dalpha tocopheryl acid sucinate),

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Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/26/04

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(920) 406-3608.

Michael P. Devereux



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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Whole Heart Multivitamin™	Vitamins B6, B12 and folic acid have been shown in clinical studies to lower homocysteine levels.*	Vitamin B6 (as pyridoxine HCI), Folic Acid, Vitamin B12 (as cyancobalamin)

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By: RISCUL

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/26/04

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Whole Heart Multivitamin™	Alpha lipoic acid, lycopene and lutein are also potent antioxidants.*	Alpha Lipoic Acid, Lycopene, Lutein (from Calendula officinalis)

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By: KLICUL

Title: Senior Vice President of Scientific Affairs

Date: 5/26/04

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Whole Heart Multivitamin™	Among regular users of supplemental vitamins, average serum homocysteine levels are reported to be 1.5 micromolar lower than those who do not supplement.*	Vitamin A (75% as beta carotene and as retinyl acetate), Vitamin C (ascorbic acid), Vitamin D (as cholecalciferol), Vitamin E (as d-alpha tocopheryl acid sucinate), Thiamin (as thiamin HCI) (vitamin B1), Riboflavin (vitamin B2), Niacin (as niacinamide and niacin), Vitamin B6 (as pyridoxine HCI), Folic Acid, Vitamin B12 (as cyancobalamin), Biotin, Pantothenic Acid (as calcium D-pantothenate), Calcium (as calcium carbonate and calcium citrate), Iodine (as potassium iodide), Magnesium (as magnesium aspartate and magnesium oxide), Zinc (as zinc gluconate), Selenium (as L-selenomethionine), Copper (as copper gluconate), Manganese (as manganese citrate), Chromium (as chromium picolinate), Molybdenum (as sodium molybdate), Sodium, Choline Bitartrate, Alpha Lipoic Acid, Lycopene, Lutein (from Calendula officinalis), Vanadium(as vanadyl sulfate), Zeaxanthin (from Calendula officinalis)

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Whole Heart	A clinical study of over 500 people	Vitamin B6 (as pyridoxine HCI), Folic Acid,
Multivitamin™	who added folic acid, Vitamin B6 and Vitamin B12 supplements to their diet, found that they experienced significant cardiovascular support.*	Vitamin B12 (as cyancobalamin)

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Br: KTICILŁ

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ENZYMATIC THERAPY & PHYTOPHARMICA*

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 • F: 888.570.6460 (Enzymatic) P: 920.469.9099 • F: 920.469.4418 (Phyto)

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Whole Heart Multivitamin™	Supports the function of cardiac mitrochondria (energy producing cells.*	Vitamin A (75% as beta carotene and as retinyl acetate)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: KLICILL

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/27/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely

Michael P. Devereux Chief Financial Officer

Whole Heart Multivitamin 24



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INTEGRATIVE THERAPEUTICS INC." NF Formulas - PhytoPharmica Tyler Encapsulations . Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 . F: 503.582.0467

OPHARMICA

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 + F: 888.570.6460 (Enzymatic) P: 920.469.9099 • F: 920.469.4418 (Phyto)

May 27, 2004

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE:

Label Claims/Disclaimers

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Whole Heart Multivitamin™	Maintains general health and vigor of epithelial cells.*	Vitamin A (75% as beta carotene and as retinyl acetate)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/21/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely.



INDORPERATED

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May 27, 2004

INTEGRATIVE THERAPEUTICS INC."

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ENZYMATIC THERAPY' & PHYTOPHARMICA'

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Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway
College Park, MD 20740

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Whole Heart Multivitamin™	Beta-carotene acts as an antioxidant to inactivate free radicals.*	Vitamin A (75% as beta carotene and as retinyl acetate)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

Ву:

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/27/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



INCOPPORATED

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May 27, 2004

INTEGRATIVE THERAPEUTICS INC."

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PRODUCT NAME	STATEMENTS INGREDIENT(S) TO WHICH THE CL/REFERS	
Whole Heart Multivitamin™	Supports the immune system.*	Vitamin C (ascorbic acid)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

hal P. Newamp

Date

5/21/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Michael P. Devereux



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INTEGRATIVE THERAPEUTICS INC."

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825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 F: 888.570.6460 (Enzymatic) P: 920.469.9099 F: 920.469.4418 (Phyto)

May 28, 2004

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Whole Heart Multivitamin™	Recent research has shown that Vitamin D is important to the maintenance of electrolyte balance, volume balance and helps support the retention of healthy blood pressure levels that are already within normal limits.*	Vitamin D (as cholecalciferol)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: FLICIL

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/28/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



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May 28, 2004

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Whole Heart Multivitamin™	Vitamin E is an antioxidant, which inhibits the oxidation of low density lipids by inactivating free	Vitamin E (as d-alpha tocopheryl acid sucinate)
	radicals.*	

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

BV: KLICILL

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/28/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely

Michael P. Devereux Chief Financial Officer

Whole Heart Multivitamin 30c



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May 28, 2004

INTEGRATIVE THERAPEUTICS INC."

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Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway
College Park, MD 20740

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Whole Heart Multivitamin™	Believed to inhibit catabolism of certain fatty acids that help form cell structures, especially membranes.*	Vitamin E (as d-alpha tocopheryl acid sucinate)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: KLICUL

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/28/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



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Tyler Encapsulations & Vitaline Formulas

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INTEGRATIVE THERAPEUTICS INC."

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May 29, 2004

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE: Label Claims/Disclaimers

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE
Whole Heart Multivitamin™	Maintains a regular heartbeat and supports healthy circulation through the pumping ability of	Thiamine (as thiamin HCI) (vitaminB1)
	the heart muscle.*	(**************************************

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: KLICILŁ

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/29/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



'NDORPORATED

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INTEGRATIVE THERAPEUTICS INC."

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ENZYMATIC THERAPY PHYTOPHARMICA'

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 • F: 888.570.6460 (Enzymatic) P: 920.469.9099 • F: 920.469.4418 (Phyto)

May 29, 2004

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE: Label Claims/Disclaimers

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE
Whole Heart Multivitamin™	benefit for heart health, and functions	Riboflavin (vitamin B2)
	synergistically with other heart healthy nutrients.*	

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/29/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Chief Financial Officer

hole Heart Multivitamin 340



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May 30, 2004

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE:

Label Claims/Disclaimers

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PRODUCT NAME		INGREDIENT(S) TO WHICH THE
		CLAIM REFERS
Whole Heart Multivitamin™	In lipid metabolism, supports healthy cholesterol	Niacin (as niacinamide and
	production and assists in triglyceride breakdown	niacin)
	to retain healthy cholesterol levels that are already	
	within normal limits.*	

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

Зv:	freest	

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/30/64

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



. INSURPERATED

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May 30, 2004

INTEGRATIVE THERAPEUTICS INC."

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Whole Heart Multivitamin™	Through peripheral vasodilatation, niacin supports	Niacin (as niacinamide and
	the retention of healthy blood pressure that is	niacin)
	already within normal limits.*	

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Kuldlill

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/30/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux Chief Financial Officer

Whole Heart Multivitamin 366



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May 30, 2004

INTEGRATIVE THERAPEUTICS INC."

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PRODUCT NAME	STATEMENTS INGREDIENT(S) TO WHICH THE
	<u>CLAIM REFERS</u>
Whole Heart Multivitamin™	In clinical studies, when combined with other heart Pantothenic Acid (as calcium D-
	healthy nutrients supported the muscle strength of pantothenate)
	the heart.*

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

Br: Kulter 1

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/30/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



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May 30, 2004

INTEGRATIVE THERAPEUTICS INC."

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Whole Heart Multivitamin™	In a clinical study of men and women who are aged from 65 to 102, an extremely significant direct correlation was found between zinc and support for healthy aortic valves.*	Pantothenic Acid (as calcium D- pantothenate)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

BV: KILYCILL

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/30/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux

Chief Financial Officer

Vhole Heart Multivitamin 40e



ENZYMATIC THERADY , NOBREDRATED

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May 30, 2004

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE
		CLAIM REFERS
Whole Heart Multivitamin™	Clinical trials have shown that zinc significantly	Pantothenic Acid (as calcium D-
	supports cardiovascular health.*	pantothenate)
		,

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/30/04

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Sincere



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May 30, 2004

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RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE
Whole Heart Multivitamin™	Research has revealed that selenium supports cardiovascular function.*	Selenium (as L- selenomethionine)
		,

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/30/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



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May 30, 2004

INTEGRATIVE THERAPEUTICS INC."

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ENZYMATIC THERAPY & PHYTOPHARMICA

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 * F: 888.570.6460 (Enzymatic) P: 920.469.9099 * F: 920.469.4418 (Phyto)

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Whole Heart Multivitamin™	Copper provides significant support for healthy heart muscles.*	Copper (as copper gluconate)

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By: KLYCUŁ

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/30/04

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May 30, 2004

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE
		CLAIM REFERS
Whole Heart Multivitamin™	Helps support the retention of healthy cholesterol	Chromium (as chromium
	levels that are already within normal limits.*	picolinate)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/30/04

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Whole Heart Multivitamin™	Supports healthy iron metabolism and supports healthy uric acid production.*	Molybdenum (as sodium molybdate)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: KIHRILL

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/30/04

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Sincerely,



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May 30, 2004

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Whole Heart Multivitamin™	Functions as a cofactor for three enzymes, which contributes to the antioxidant capacity of the blood and also plays a role in the metabolism of drugs and toxins.*	Molybdenum (as sodium molybdate)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/30/64

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Sincerely,



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PRODUCT NAME	STATEMENTS 100 100 100 100 100 100 100 100 100 10	INGREDIENT(S) TO WHICH THE
		CLAIM REFERS
Whole Heart Multivitamin™	An antioxidant that supports the retention of healthy cholesterol and blood pressure levels that are already within normal limits.* Also helps maintain healthy heart pumping ability.*	Alpha Lipoic Acid

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: _____

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/30/04

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Sincerely

Michael P. Devereux



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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE
		CLAIM REFERS
Whole Heart Multivitamin™	An antioxidant that provides protection to the	Lycopene
	inside surfaces of artery walls.*	
	·	

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By: Kuldlillet

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/30/04

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Whole Heart Multivitamin™	An antioxidant plays a role in the antioxidant cascade that neutralizes the energy of reactive oxygen.*	Lutein

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Kildlillit

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

whil P. Neverme

Date: 5/30/04

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Whole Heart Multivitamin™	An essential trace element supports glucose and lipid metabolism.*	Vanadium

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

Βv

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

P. Nevemp

Date: 5/30/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely

Michael P. Devereux Chief Financial Officer

Vhole Heart Multivitamin 50e



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RE: Label Claims/Disclaimers

e Heart Multivitamin 51

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Whole Heart Multivitamin™	Research has demonstrated that the reduction of elevated homocysteine levels and prevention of free radical formation supports cardiovascular health. The specific vitamins, homocysteine lowering agents and antioxidants in Whole Heart Health Multivitamin have been shown to provide superior nutritional support for heart health, support the reduction of elevated homocysteine levels, and interfere with free radical formation.*	Vitamin A (75% as beta carotene and as retinyl acetate), Vitamin C (ascorbic acid), Vitamin D (as cholecalciferol), Vitamin E (as d-alpha tocopheryl acid sucinate), Thiamin (as thiamin HCI) (vitamin B1), Riboflavin (vitamin B2), Niacin (as niacinamide and niacin), Vitamin B6 (as pyridoxine HCI), Folic Acid, Vitamin B12 (as cyancobalamin), Biotin, Pantothenic Acid (as calcium D-pantothenate), Calcium (as calcium carbonate and calcium citrate), Iodine (as potassium iodide), Magnesium (as magnesium aspartate and magnesium oxide), Zinc (as zinc gluconate), Selenium (as L-selenomethionine), Copper (as copper gluconate), Manganese (as manganese citrate), Chromium (as chromium picolinate), Molybdenum (as sodium molybdate), Sodium, Choline Bitartrate, Alpha Lipoic Acid, Lycopene, Lutein (from Calendula officinalis), Vanadium(as vanadyl sulfate), Zeaxanthin (from Calendula officinalis)

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By: Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/30/04

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